DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 18, 2015

Pelton & Crane
Mr. Frank Ray
Regulatory Affairs Manager
11727 Fruehauf Dr.
Charlotte, North Carolina 28273

Re: K143696
Trade/Device Name: Spirit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 19, 2015
Received: August 21, 2015

Dear Mr. Ray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K143696

Device Name

Spirit

Indications for Use *(Describe)*

The Spirit Dental Operative Units are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to hand held dental instruments. The Spirit Dental Operative Units are intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section V – 510(k) Summary
for
Spirit

1. Submitter Information:

Pelton & Crane
11727 Fruehauf Drive
Charlotte, NC 28273

Contact Person: Frank Ray
Telephone Number: (704) 587-7227
Fax Number: (704) 587-7250

Date Prepared: December 19, 2014

2. Device Name:

- Proprietary Name: SPIRIT
- Common Name: Dental Delivery Unit
- Classification Name: Unit, Operative Dental
- CFR Number: 872.6640
- Device Class: I
- Product Code: EIA

3. Predicate Device:

- Proprietary Name: ELEVANCE - (K120239)
- Common Name: Dental Delivery Unit
- Classification Name: Unit, Operative Dental
- CFR Number: 872.6640
- Device Class: I
- Product Code: EIA

4. Description of Device:

The Spirit Dental Operative Units serves as a base that includes components to deliver air, water, electrical power, and vacuum to dental handpieces, instruments, and accessories. The controls are contained in a Doctor's Unit, an Assistant's Unit, and a Cuspidor. Additional parts include mount arms, foot control, and a junction box that houses a power supply and air/water regulators. Various Handpieces and accessories can be added to the Spirit Dental Operative Unit which Pelton & Crane does not manufacture but does provide a means to connect them into the Sprit Dental Operative Units. These include, but not limited to, pneumatic handpieces,

electric motors with handpieces, scalers, intra-oral cameras, curing lights, air/water syringes, SE and HVE vacuum instruments.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Pelton & Crane is bundling the Spirit dental operative unit models listed in Table 5.1 below as the models do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence. The device description and intended use are identical for all configuration models listed in Table 5.1 below. The differences between the three series and mounting configurations are cosmetic in nature such as size/shape of the delivery head, mount arms, and instrument hangers. All critical components within the Spirit Dental Operative units are common.

The Spirit Dental Operative Units are available in three different series (3000, 2000, and 1000) which are offered in various mounting configurations such as chair mount traditional delivery, chair ellipse delivery, cabinet mount delivery, wall mount delivery, cart delivery, flexible work station delivery, and mobile work station delivery. The various mounting configurations for the Spirit dental operative units are illustrated within the Use and Care manuals. The differences between the Spirit 3000, 2000, and 1000 series are the Spirit 3000 series are the premier level dental operative units, the Spirit 2000 series are the mid-level dental operative units, and the Spirit 1000 series are the economy level dental operative units.

Table 5.1

Series	Model	Description	Integrated Dual Electric Motors (previously cleared under K103027 and K080677)
3000	SDW 30	Spirit 3000 Wall Delivery	Optional
3000	SDC 30	Spirit 3000 Cabinet Delivery	Optional
3000	SCT30	Spirit 3000 OTP w/Traditional Delivery	Optional
3000	SET30	Spirit 3000 OTP Ellipse w/Traditional Delivery	Optional
3000	FWS30	Spirit 3000 Flexible Work Station (Renaissance)	Optional
2000	SCT20	Spirit 2000 OTP w/Traditional Delivery	N/A
2000	SET20	Spirit 2000 OTP Ellipse w/Traditional Delivery	N/A
2000	SDW-D	Spirit 2000 Wall Delivery	N/A
2000	SDC-D	Spirit 2000 Cabinet Delivery	N/A
2000	MWS-C	Spirit 2500 Mobile Work Station	N/A
2000	FWS-C	Spirit 2000 Flexible Work Station (Centennial)	N/A
2000	FCT-C	Spirit 2000 Flexible Cart	N/A
1000	SCT15	Spirit 1500 OTP w/Traditional Delivery	N/A
1000	SET15	Spirit 1500 OTP Ellipse w/Traditional Delivery	N/A
1000	SCE15	Spirit 1500 OTP w/Euro Delivery	N/A
1000	SEE15	Spirit 1500 OTP Ellipse w/Euro Delivery	N/A
1000	CRT15	Spirit 1500 Cart	N/A
1000	SDWD15	Spirit 1500 Wall Delivery	N/A
1000	SDCD15	Spirit 1500 Cabinet Delivery	N/A
1000	CD15	Spirit 1500 Cabinet Delivery	N/A
1000	SCT17	Spirit 1700 OTP w/Traditional Delivery	N/A
1000	SET17	Spirit 1700 OTP Ellipse w/Traditional Delivery	N/A
1000	RE15	Spirit Cuspidor/PMU/Assistant's Unit	N/A

2000 1000	AV	Spirit Cabinet Mount Assistant's Unit	N/A
3000 2000 1000	RM	Spirit Rear Chair Mount Assistant's Unit	N/A
1000	EX 15	Spirit Executive Dental Unit	N/A

The Pelton & Crane Spirit dental operative units can also be equipped with available and already marketed Pelton & Crane products. These products include:

- Tip-A-Dilly Tip
- Tip-A-Dilly
- Tip - A
- Tip - D
- Tip - E
- Tip - F
- Tip - C

Optional accessories (devices) from other manufacturers that are integrated/attached to the Spirit dental operative units have already been cleared by the FDA.

Principle of Operation:

The delivery head is mounted to an arm mechanism for support and positioning of the delivery head around the patient. The types of mounting configurations include chair, cabinet, wall, cart, and floor mounts as illustrated within the Use and Care manuals. Depending on mounting configuration, a junction box or utility center provides housing for connections to the facility air, water, vacuum, and power sources, regulators for air and water, and transformers for optional integrated accessories. Regulated air and water, source vacuum, and power tubing and cables are routed through the mounting arms to the delivery head where the utilities are distributed to the individual dental instruments with a handpiece control system contained in the delivery head.

The handpiece control system is a pneumatic control system that distributes utilities to desired instruments that acts as "selected" instrument once removed from the respective instrument holder. The foot control activates the handpiece drive air, coolant air and water. Individual handpiece drive air and water flow adjustments are individually controlled by the operator via the control block and control valves. The delivery head is provided with master on-off switch to control air/water flow.

An optional foot control may be integrated into the system that acts as an intermediate manual user control for air and water activation to a selected instrument.

Suction instruments are not activated with the handpiece control system as the vacuum supply is manually controlled by the user with a flow control valve integrated in the instrument body. Also, air and water syringes are not activated with the handpiece control system as air and water flow is manually opened and closed with button actuated valves integrated into the syringe body.

Some handpieces may be power driven. The delivery head is provided with low voltage power to drive these handpieces. For some single and dual electrically driven motor configurations, the delivery system utilizes components and software from the device manufacturer, Kaltenbach & Voigt GMBH which was approved under 510(k) K103027 (ELECTROtorque TLC) and K080677 (COMFORTronic 4894 and COMFORTdrive 200XDA Handpiece) to control features and functionality of the motor(s). The Spirit dental operative unit provides the means to internally mount and house the electrically driven motor control and handpiece components and the utilities needed for operation (air, water, and low-voltage electricity). For the dual electrically driven motor configuration, an air activated switching board is used to drive the motors from one control board.

5. Indications for Use:

The Spirit dental operative units are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to hand held dental instruments. The Spirit dental operative units are intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory.

6. Description of Substantial Equivalence:
Technological Characteristics:

The Spirit Dental Operative Units, manufactured by Pelton & Crane, is being modified to have the ability to control two (2) electric motors. The Spirit Dental Operative Units has the same intended use as previously cleared Elevance Dental Operative Unit (K120239), manufactured by Midmark Corporation, but does have different technological characteristics. However, these different technological characteristics do not raise new concerns of substantial equivalence. The performance data and testing of the Pelton & Crane Spirit Dental Operative Units demonstrates substantial equivalence to the Midmark Elevance Dental Delivery Unit. Hence, the device is substantially equivalent.

Table 5.2

Feature	Midmark Elevance Dental Delivery Unit (K120239)	Pelton & Crane Spirit Dental Operative Unit
Indications for Use	Midmark instrument delivery systems are intended to provide dental professionals with air, water, and suction along with low-voltage electricity to operate dental handpieces, syringes, and accessories during dental examinations and treatments.	The Spirit Dental Operative Units are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to hand held dental instruments. The Spirit Dental Operative Units are intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory.
Regulation Number	21 CFR 872.6640	Same
Regulation Title	Dental operative unit and accessories	Same

Feature	Midmark Elevance Dental Delivery Unit (K120239)	Pelton & Crane Spirit Dental Operative Unit
Regulation Class	I	Same
Product Code	EIA	Same
Device Classifications (Electrical)	Class I, Type B applied part, IPX0, continuous operation	Same
Utilities and Standards		
Transportation / Storage temperature	23°F to 100°F	-68°F to 122°F
Relative humidity range	10% to 90%	Same
Operating temperature range	59°F to 95°F	68°F to 76°F
Air supply pressure range	80-100 psi	80-105 psi
Air/oil separator	Gauze	Same
Water supply pressure range	30-50 psi	40-80 psi
Isolated water bottle system	Optional	Same
Standards	EN 60601-1-2:2007 Part 1-2 EN 61000-3-:2006+A1:2009 +A2:2009 Part 3-2 IEC 60601-1 Part 1 ISO 7494-1:2004 ISO 7494-2:2003	EN 60601-1-2:2007 Part 1-2 EN 61000-3-2:2006+A1:2009 +A2:2009 Part 3-2 ES 60601 -1 Part 1 ISO 7494-1:2004[1] ISO 7494-2:2003[1]
User / Service Interface		
Number of user accounts	Three	One[2]
Setting display	LED screen	LCD screen[2]
Screen navigation	Navigation arrows	Same
Software updates	Via external USB port	Via internal 10-pin port[2]
Error tracking	Offered	Same
Built-in diagnostics	Offered	Same
Hand Held Devices		
Optional accessories	Air/water syringe Saliva ejector HVE Up to 2 micro motors Scaler Camera Curing light	Same

Feature	Midmark Elevance Dental Delivery Unit (K120239)	Pelton & Crane Spirit Dental Operative Unit
	Pneumatic motor	
Accessory connection	Integrated	Same
Number of hand piece locations	4-6	Same
Hand piece control system	Kink Valve	Valve block
Syringe water flow control	Adjustable	Same
Syringe air flow control	Adjustable	Same
Coolant air flow control	Adjustable	Same
Hand piece air and water bypass	Offered	Not applicable[3]
Number of hand piece presets	Five	Six[2]
Remote hand piece activation with water toggle	Via foot control	Same
Positioning		
Delivery unit head positioning	Flex arm	Same
Flex arm brake release	Integrated	Same
Maximum load on flex arm mounted units	10 lbs.	Same[4]
Additional Features		
Endodontic capability	Offered	Same
Hand piece flush	Standard feature	Same
Air/Water quick connect ports	Offered	Same
Light control	Offered	Same
Tray options	Three	One[2]
Unit configurations for dominant hand	Left/Right	Same

[1] The Spirit Dental Operative Unit meets all requirements found in ISO 7494-1 and ISO 7494-2

[2] These differences do not affect substantial equivalence as they are only differences in marketing features between the proposed device and the predicate device

[3] Hand piece air and water by pass is not necessary for the Spirit Dental Operative Unit as both air and water are pneumatically controlled rather than electronically controlled.

[4] In the Spirit Dental Operative Unit manuals, it states: "The maximum weight capacity for the control head is 3 lbs." However, this only notes the limit of additional weight that can be placed on the control head. When considering the load of the control head itself and included accessories, the maximum load on the flex arm is 10 lbs.

Performance Data:

Electrical, mechanical, and performance testing according to standard AAMI ES60601-1, was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. The Pelton & Crane Spirit dental operative units passed all tests. In addition to testing governed by regulatory standards, additional testing was conducted to ensure the technological characteristic differences between the Pelton & Crane Spirit Dental Operative Units and the predicate device, the Midmark Elevance Dental Delivery Unit (K120239), did not present any new concerns about substantial equivalence. The Pelton & Crane Spirit Dental Operative Unit passed all tests. Hence, the device demonstrates substantial equivalence.

Substantial equivalence of the Spirit dental operative unit with dual electric motors has been successfully evaluated with passing results via validation and verification testing.

Electrical Safety and EMC testing on the Spirit dental operative unit with dual electric motors was performed to confirm conformance.

Biocompatibility evaluation was conducted on patient contacting parts and found to be in conformance with ISO 10993-1.

Additionally, the Spirit Dental operative unit software was successfully validated to confirm the performance of the device per AMMI ANSI IEC 62304:2006 Medical Device Software. Software for the dual electric motors from the device manufacturer, Kaltenbach & Voigt GMBH has already been cleared under 510(k) K103027 (ELECTROtorque TLC) and K080677 (COMFORTronic 4894 and COMFORTdrive 200XDA Handpiece). These two 510(k) devices are being integrated into the Spirit Dental Operative units and are listed in the optional accessories (devices) table. The testing also considered FDA Software Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on the comparison of intended use, technological characteristics, and performance data, the minor differences between the Spirit dental operative units with dual electric motors, and the predicate device, ELEVANCE Delivery Unit (K120239), do not raise new concerns regarding substantial equivalence for the proposed indications of use. Pelton & Crane concludes that the Spirit dental operative units are substantially equivalent to the predicate device.